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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,047	12/06/2001	Theodora Ross	UM-06692	6232

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,047	ROSS ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12-18,23-29,36 and 84-93* is/are pending in the application.

4a) Of the above claim(s) *84-86 and 91-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 12-18, 23-29, 36 and 87-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Sequence comparison for US 6,974,501.

Response to the Amendment

The Amendment filed on 05/18/2005 in response to the previous Final Office Action (03/17/2005) is acknowledged and has been entered. Upon careful review and reconsideration, the finality of the previous Final Office Action (03/17/2005) has been withdrawn.

Claims 9, 12-18, 23-29, 36, and 84-93 are currently pending.

Claims 84-86 and 91-93 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 9, 12-18, 23-29, 36 and 87-90 is currently pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 12-18, 23-29, 36, and 87-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive a genus of reagents such as a nucleic acid probe complementary to at least a portion of HIP1 mRNA configured to detect HIP1 having a nucleic acid sequence of SEQ ID NO: 1. However, the written description in this case only sets forth one species of reagents configured to detect HIP1 consisting of the nucleic acid sequence of

SEQ ID NO: 1, wherein the reagent is a nucleic acid probe completely complementary to a HIP1 mRNA fragment consisting of the nucleotide sequence of SEQ ID NO: 1.

The specification teaches (page 13, line 29 to page 14, line 2) that reagents capable of specifically detecting HIP1 expression refers to reagents used to detect the expression of HIP1 including, but not limited to, nucleic acid probes capable of specifically hybridizing to HIP1 mRNA. The specification further teaches (page 36, lines 5-7) that RNA expression may be detected by hybridization of a complementary labeled probe, wherein that complementary molecule includes polynucleotides (i.e., a sequence of nucleotides) related by the base-pairing rules, e.g., for the sequence "A-G-T", is complementary to the sequence "T-C-A" (page 21, lines 1-3). The specification teaches (page 21, lines 4-8) that complementary further includes "partial" in which only some of the nucleic acids' bases are matched according to the base pairing rules, as well as, "complete" or "total" complementarity between nucleic acids, wherein the degree of complementarity between nucleic acid strands has a significant effect on the efficacy and strength of hybridization between nucleic acid strands. Thus, while the specification contemplates employing nucleic acid probes completely or partially complementary to HIP1 mRNA for the detection of HIP1 having a nucleic acid sequence of SEQ ID NO: 1, such contemplation does not extrapolate to the possession of any and/or all polynucleotides partially or completely complementary to at least a portion of HIP1 mRNA having a nucleotide sequence of SEQ ID NO: 1. Some of the factual considerations that are weighed when determining a written description include the level of skill and knowledge in the art, the disclosure of complete or partial structures, the disclosure of physical and or chemical properties, adequate disclosure of the functional characteristics, the correlation between structure and function, and disclosure of methods of making. In the instant case, the claims recite HIP1 having the nucleotide sequence of SEQ ID NO: 1 which in the context of cDNA permits the inclusion of other moieties, see Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997). However, the specification (Figure 7 and Figure 9) only adequately describes the complete chemical, structural, and functional properties of the cDNA for HIP1 (SEQ ID NO: 1) and for mutated HIP1 (SEQ ID NO: 3). The specification does not appear to disclose any other sequences having the nucleotide sequence of SEQ ID NO: 1, nor does the specification disclose any nucleic acid probes complementary to at least a portion of HIP1 mRNA for detecting HIP1 having a nucleic acid sequence of SEQ ID NO: 1. The written description only

reasonably conveys a one species of reagents configured to detect HIP1 consisting of the nucleic acid sequence of SEQ ID NO: 1, wherein the reagent is a nucleic acid probe completely complementary to a HIP1 mRNA fragment consisting of the nucleotide sequence of SEQ ID NO: 1; and therefore, is not commensurate with the full scope of any reagent such as a complement to at least a portion of a HIP1 mRNA having the nucleic acid sequence of SEQ ID NO: 1. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The Office has published a synopsis of written description guidelines (available at <http://www.uspto.gov/web/menu/written.pdf>>) with particular emphasis on the claiming of partial nucleic acid segments (see Example 7 and Example 9) that encompass a genus of polynucleotides, i.e. any nucleic acid complementary to at least a portion of HIP1 mRNA having a nucleic acid sequence of SEQ ID NO: 1. The guidelines note (Example 7, page 31) that the examiner "must evaluate" any necessary common attributes or features when reviewing a claim that encompasses a widely varying genus. And, as set forth previously, the disclosure fails to describe the common attributes or characteristics that identify members of the genus. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of partial and/or complete complements to HIP1 mRNA having a nucleic acid sequence of SEQ ID NO: 1 that encompass the genus of reagents nor does it provide a description of structural features that are common to the compounds. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of reagents which are complements to at least a portion of HIP1 mRNA having a nucleic acid sequence of SEQ ID NO: 1, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a reagent, wherein the reagent is a nucleic acid probe completely complementary to a HIP1 mRNA fragment consisting of the nucleotide sequence of SEQ ID NO: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 12-18 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 6,794,501, 05/2001).

Chen et al. teach (column 6, lines 5-13) a method of diagnosing colon cancer in a subject comprising obtaining a biological sample from a subject and determining the expression of at least tow colon cancer-associated nucleic acid molecules in a sample, wherein the expression is diagnostic of colon cancer. With regards to the nucleic acid, the patent teaches a nucleic acid molecule which has 56.9% sequence similarity from nucleotides 619 to 3118 of the presently claimed nucleic acid of SEQ ID NO: 1 (see attached sequence comparison). With regards to the sample, Chen et al. teach (column 6, lines 21-24) that the sample includes, but is not limited to, colorectal tissue and/or blood. With regards to detecting, the patent teaches (column 11, lines 29-70 and column 23, lines 45+) the detecting the nucleic acid comprises detecting RNA expression by using direct RNA amplification, reverse transcription of RNA to cDNA or by nucleic acid microarray technology. Chen et al. further teach that the detection of the nucleic acid may comprise exposing a probe with a nucleic acid sequence that perfectly matches the target sequence. Furthermore, the patent teaches (page 6, lines 30+) a method of providing a prognosis to a subject comprising determining the expression level of the nucleic acid. Thus, while Chen et al. does not teach that the probe is "complementary", the claimed functional limitation would be an inherent property of the referenced method since the specification discusses (page 21, lines 1-9) that the term complementary is used in reference to nucleic acid bases which are matched according to the base pairing rules. Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

The following prior art is provided and made of record (although not relied upon) is considered pertinent to applicant's disclosure:

Mack et al. (WO 00/55633 A2, 2000) discloses HIP2 expressed in colon tumors compared to normal tissues (Figure 19/236).

Therefore, NO claim is allowed.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER